CENTRAL FAX CENTER APR 0 8 2008

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SERIAL NO.:

10/553,770

CONFIRMATION NO.

7743

APPLICANT:

Schmitt et al.

FILED:

June 19, 2006

GROUP ART UNIT:

3768

**EXAMINER:** 

Bor, Helene Catherine

ATTORNEY DOCKET

PHDE030127US

NO.:

CUSTOMER NO.:

38107

FOR:

APPARATUS FOR ANGIOGRAPHIC X-RAY PHOTOGRAPHY

Mail Stop Appeal Brief - Patents Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

**DATE: April 8, 2008** 

#### APPEAL BRIEF

Sir:

The Notification of Appeal was filed on February 12, 2008.

#### DEPOSIT ACCOUNT

The Patent Office is authorized to charge any fees associated with this filling to our deposit account no. 14-1270

Douglas B. McKnight, Reg. No. 50,447

CERTIFICATE OF FACSIMILE TRANSMISSION

I certify that this Appeal Brief is being filed on the date indicated below by Facsimile transmission with the United States Patent

and Trademark Office. april 8 2008

Patricia A. Heim

## TABLE OF CONTENTS

I.	REAL PARTY IN INTEREST	Page 3
п.	RELATED APPEALS AND INTERFERENCES	Page 4
ш.	STATUS OF CLAIMS	Page 5
IV.	STATUS OF AMENDMENTS	Page 6
v.	SUMMARY OF CLAIMED SUBJECT MATTER	Page 7
VI.	GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL	Page 10
VII.	ARGUMENTS	Page 11
	CLAIMS APPENDIX	Page 20
	EVIDENCE APPENDIX	Page 25
IX.	RELATED PROCEEDINGS APPENDIX	Page 26
¥	R N.I. A. I. H.I. F. TR.I. P.	_

(WP487234:1)

**2**003

U.S. Serial No. 10/553,770 Appeal Brief Dated April 7, 2008

#### REAL PARTY IN INTEREST I.

The real party in interest in connection with the above identified patent application is Koninklijke Philips Electronics, N.V., the assignee of record.

## II. RELATED APPEALS AND INTERFERENCES

There exist no related appeals or interferences in connection with the above-identified patent application.

### III. STATUS OF CLAIMS

Claims 1-10 and 12 were pending in this application and stand rejected. Claim 11 has been cancelled. Claims 1-10 and 12 are being appealed.

## IV. STATUS OF AMENDMENTS

Amendments to claims 1, 5, 7 and 8 were filed after issuance of the final Office Action dated November 23, 2007, which were entered as per the Advisory Action of February 8, 2008. All previous amendments have been entered.

## RECEIVED CENTRAL FAX CENTER APR 0 8 2008

## V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed to an X-ray imaging device with computer means which is provided for visualizing blood flow in a coronary vascular tree of a patient. (page 5, lines 12-25). The visualization is effected based on data which contain a first set of X-ray projection images (1) of the vascular tree in various phases of a heart cycle, a first ECG (2) of the patient recorded simultaneously with the first set, a second set of X-ray projection images (6) recorded during or after administration of a contrast agent and a second ECG (7) of the patient recorded simultaneously with the second set. (page 5, lines 12-25; page 5, lines 26-29; FIG. 1, ref. 1, 2, 6, 7). The computer means comprise a program control which operates in accordance with the method steps for determining a time-dependent concentration of the contrast agent within a threedimensional structure of the vascular tree. (page 5, line 30 through page 6, line 5). The method steps include reconstruction of the three-dimensional structure of the vascular tree during the various phases of the heart cycle using the first set of X-ray projection images (1) and splitting of the structure into a number of vascular segments (5). (page 5, lines 12-25; FIG. 1, ref. 1, 5). The method steps include determining the time-dependent concentration of the contrast agent within the reconstructed three-dimensional structure of the vascular tree by a) assignment of the second set of X-ray projection images (6) to a respective phase of the heart cycle using the recorded second ECG (7); b) finding local image areas assigned to the individual vascular segments within the second set of X-ray projection images (6) corresponding to spatial positions of the vascular segments in the respective phase of the heart cycle according to the three-dimensional structure of the vascular tree; and c) determining the concentration of the contrast agent within the vascular segments (8) by evaluating an X-ray absorption within the local image areas found in the method step b). (page 5, lines 26-29; page 5, line 30 through page 6, line 5; FIG. 1, ref. 6, 7, 8). The method steps include visualization of flow of the contrast agent through the threedimensional structure of the vascular tree according to the time-dependent concentration of contrast agent, wherein the recording of the first and second set of X-ray projection images (1, 6) is effected at a plurality of projection angles. (page 5, line 30 through page 6, line 5; page 6, lines 6-19; FIG. 1, ref. 1, 6, 9).

Claim 7 is directed to a computer program for an X-ray imaging device for visualization of the blood flow in a coronary vascular tree of a patient. (page 5, lines 12-25; page 6, lines 6-19). The computer program receives as input variables data which contain a first set of X-ray projection images (1) of the vascular tree in various phases of a heart cycle, a first ECG (2) of the patient recorded simultaneously with the first set, a second set of X-ray projection images (6) recorded during or after the administration of a contrast agent and a second ECG (7) of the patient recorded simultaneously with the second set. (page 5, lines 12-25; page 5, lines 26-29; FIG. 1, ref. 1, 2, 6, 7). The computer program on the computer means of the X-ray imaging device implements a program control which operates in accordance with method steps for determining a time-dependent concentration of the contrast agent within a three-dimensional structure of the vascular tree. (page 5, line 30 through page 6, line 5). The method steps include reconstruction of the three-dimensional structure of the vascular tree during the various phases of the heart cycle using the first set of X-ray projection images (1) and splitting of the structure into a number of vascular segments (5)! (page 5, lines 12-25; FIG. 1, ref. 1, 5). The method steps include determining the time-dependent concentration of the contrast agent within the reconstructed three-dimensional structure of the vascular tree by a) assignment of the X-ray projection images of the second set (6) to a respective phase of the heart cycle using the recorded second ECG (7), b) finding local image areas assigned to the individual vascular segments within the X-ray projection images of the second set (6) that correspond to spatial positions of the vascular segments in the respective phase of the heart cycle according to the three-dimensional structure of the vascular tree; and c) determining the concentration of the contrast agent within the vascular segments (8) by evaluating an X-ray absorption within the local image areas found in the method step b). (page 5, lines 26-29; page 5, line 30 through page 6, line 5; FIG. 1, ref. 6, 7, 8). The method includes visualization of flow of the contrast agent through the threedimensional structure of the vascular tree according to the time-dependent concentration of the contrast agent, wherein the recording of the first and second set of X-ray projection images (1, 6) is effected at a plurality of projection angles. (page 5, line 30 through page 6, line 5; page 6, lines 6-19; FIG. 1, ref. 1, 6, 9).

Claim 8 is directed to an X-ray imaging method for visualizing blood flow in a coronary vascular tree of a patient. (page 5, lines 12-25). The method includes a) recording a first set of X-ray projection images (1) of the vascular tree during various phases of a heart cycle while simultaneously recording a first ECG (2) of the patient, where the recording of the first set of Xray projection images are performed at a plurality of projection angles; b) reconstruction of a three-dimensional structure of the vascular tree during the various phases of the heart cycle from the first set of X-ray projection images (1) and splitting of the structure into a number of vascular segments (5); c) recording of a second set of X-ray projection images (6) of the vascular tree during or after administration of a contrast agent while a second ECG (7) of the patient is being recorded, where the recording of the second set of X-ray projection images is performed at a plurality of projection angles; and d) determining a time-dependent concentration of the contrast agent within a three-dimensional structure of the vascular tree as reconstructed in the method step b). (page 5, lines 12-25; page 5, lines 26-29; page 5, line 30 through page 6, line 5; page 6, lines 6-19; FIG. 1, ref. 1, 2, 5, 6, 7). The time-dependent concentration is performed by aa) assignment of the X-ray projection images of the second set (6) to a respective phase of the heart cycle using the recorded second ECG (7); bb) finding local image areas assigned to the individual vascular segments within the X-ray projection images of the second set (6) corresponding to spatial positions of the vascular segments in the respective phase of the heart cycle according to the three-dimensional structure of the vascular tree; and cc) determining the concentration of the contrast agent within the vascular segments (8) by evaluating an X-ray absorption within the local image areas found in the method step bb). (page 5, lines 26-29; page 5, line 30 through page 6, line 5; FIG. 1, ref. 6, 7, 8). The method also includes visualization of flow of the contrast agent through the three-dimensional structure of the vascular tree according to a time-dependent concentration of the contrast agent determined in method step d). (page 5, line 30 through page 6, line 5; FIG. 1, ref. 9).

# VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are requested to be reviewed on appeal. In particular, the Examiner rejected claims 1-10 and 12 under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 6,442,235 to Koppe in view of United States Patent No. 7,180,976 to Wink.

### VII. ARGUMENTS

## i. REJECTION OF CLAYMS 1-10 and 12 UNDER 35 U.S.C. § 103(a)

#### a. Claims 1-7

The Examiner rejected claims 1-7 under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 6,442,235 to Koppe in view of United States Patent No. 7,180,976 to Wink. The Examiner asserted that Koppe includes all of the features of independent claims 1 and 7 except for the recording and utilization of any ECG in the imaging process. The Examiner asserted that it would have been obvious to modify Koppe with utilization of ECG recordings as described in claims 1 and 7 based upon the teachings of Wink in order to "determine the optimal viewing of the coronary tree" and in order to "improve volumetric reconstruction." (Final Office Action page 5, first paragraph). The Examiner also conceded that Koppe obtains its second set of x-ray images from a fixed position when utilizing dual x-ray detectors but asserts that when a single x-ray detector is utilized then two sets of x-ray images are taken from a plurality of projection angles. (Advisory Action page 2).

Claims 1-7 include the features of determining the time-dependent concentration of the contrast agent within the reconstructed three-dimensional structure of the vascular tree by a) assignment of the second set of X-ray projection images to a respective phase of the heart cycle using the recorded second ECG; b) finding local image areas assigned to the individual vascular segments within the second set of X-ray projection images corresponding to spatial positions of the vascular segments in the respective phase of the heart cycle according to the three-dimensional structure of the vascular tree; and c) determining the concentration of the contrast agent within the vascular segments by evaluating an X-ray absorption within the local image areas found in the method step b).

Applicants disagree with the Examiner's conclusion of obviousness and assert that modifying Koppe to include the claimed recording and utilization of ECG signals is mere

hindsight analysis. Koppe is directed towards a method of imaging blood flow as a function of time:

The invention is based on the recognition of the fact that an image data set, which may be a two-dimensional or a three-dimensional image data set and contains information concerning the course of the blood vessels in the object to be examined, can be encoded in time in such a manner that it also contains information concerning the blood flow as a function of time. Such encoding in time is performed according to the invention in that the image data set is compared with a series of X-ray projection images; these X-ray projection images are formed successively in time and contain the information concerning the distribution of an injected contrast medium in the blood vessels at each time a different instant. Because each X-ray projection image is individually compared with the image data set, that is, each image value of the image data set is compared with the image values of the individual X-ray projection images, it is quasi checked which parts of the vascular system contained in the image data set are filled with the contrast medium at the individual instants associated with the respective X-ray projection images. Using suitable reproduction methods, the image data set thus encoded in time can be converted into one or more images which show the blood flow as a function of time. (Koppe col. 1, line 48 through col. 2, line 3)(emphasis added).

One of ordinary skill in the art would not replace the particular technique and sequenced steps described in *Koppe* with the claimed steps of assigning of a second set of X-ray projection images to a respective phase of the heart cycle using a recorded second ECG; finding local image areas assigned to the individual vascular segments within the second set of X-ray projection images corresponding to spatial positions of the vascular segments in the respective phase of the heart cycle according to the three-dimensional structure of the vascular tree; and determining the concentration of the contrast agent within the vascular segments by evaluating an X-ray absorption within the local image areas found.

Additionally, Wink is directed towards a method of three-dimensional reconstruction imaging using rotational angiography:

The presented novel method includes creation of a surface model of a selected segment of interest of the cardiac arterial tree based on projections from a rotational acquisition. The method has the potential to build a model based on every projection that captures the heart at the same phase. The combination of the partial model of the segment of interest with the automatic volumetric reconstruction of the entire coronary tree using all of the acquired projections, without regard to the cardiac phase, is used for visualization of the main vessels of the coronary tree and to determine the 'optimal working view' with reduced vessel overlap and without the need to manually create a surface model of the entire coronary tree, thereby reducing reconstruction time making the process more useful for real time clinical application. (Wink col. 5, lines 44-58)(emphasis added).

The objective of *Koppe* is to "enable] the reproduction of the blood flow in an object to be examined as a function of time" which is accomplished by "time encoding of the X-ray image data set." (*Koppe* col. 1, lines 33-37 and col. 2, lines 17-18). As pointed out above, *Wink* describes combining a partial vascular model with a complete volumetric reconstruction of the coronary tree without regard to the cardiac phase for visualization and optimal working view. One of ordinary skill in the art would not look towards modifying *Koppe* to include the recording and utilization of ECG signals based on the Examiner's suggested modification of determining an optimal view or improving volumetric reconstruction. "The TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence – teachings, suggestions (a tellingly broad term), or motivations (an equally broad term) – that arise before the time of invention as the statute requires." Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories 2007-1223 p. 11 (Fed. Cir. March 31, 2008)

Moreover, claims 1-7 include the features of reconstruction of a three-dimensional structure of the vascular tree during the various phases of the heart cycle using a first set of X-ray projection images where the recording of the first set of X-ray projection images is effected at a plurality of projection angles and finding local image areas assigned to individual vascular segments within a second set of X-ray projection images corresponding to spatial positions of the

(WP487234;1)

vascular segments in the respective phase of the heart cycle where the recording of the second set of X-ray projection images is effected at a plurality of projection angles. Koppe describes a first technique for imaging blood flow as a function of time as follows:

The invention will be illustrated hereinafter on the basis of the flow chart of a first version of the method according to the invention which is shown in FIG. 2. After the initialization (step 100) and after a contrast medium injection, the C-arm 10 is step-wise rotated about its center and at the same time a series of m X-ray projection images D<sub>i</sub> (for example, m=100) is formed, which projection images represent the object 3 to be examined and the blood vessels that are present therein and are filled with a contrast medium, from different perspectives (step 101). The X-ray projection images D<sub>i</sub> constitute a three-dimensional X-ray image data set K.

During a step 102 which takes place at the same time or at a later instant (after a further contrast medium injection), the imaging unit 12', 13' acquires a second series of X-ray projection images E<sub>i</sub> from a fixed perspective. During the subsequent step 103 on the one hand correction is made for imaging errors which are due, for example, to the imperfection of the imaging device or to the mechanical deformation of the C-arm. On the other hand a three-dimensional reconstruction image R is formed from the X-ray projection images D<sub>i</sub> by means of a known reconstruction algorithm. In the step 104 a reconstruction sub-image R' is formed from said reconstruction image R, which reconstruction sub-image contains, mainly or exclusively, information concerning the course of the blood vessels in the region examined. This reconstruction sub-image R' contains q voxels V<sub>k</sub> which are characterized by their co-ordinates in space. (Koppe col. 4, lines 28-55)(emphasis added).

Koppe further describes another reconstruction technique as follows:

A reconstruction sub-image R' can also be obtained in a manner other than that described with reference to FIG. 2, for example, by subtraction angiography. To this end, two series of X-ray projection images are formed from different X-ray positions by means of the imaging unit 12, 13, that is, once with and once without administration of contrast medium. The X-ray projection images of the two series that are formed from each time the same X-ray position are then subtracted from one another and the resultant projection images are reconstructed so as to form the desired reconstruction sub-image R'. (Koppe col. 6, lines 3-13).

(WP487234;1)

This latter technique in *Koppe* is relied upon by the Examiner for teaching the claimed features of reconstruction of a three-dimensional structure of the vascular tree using a first set of X-ray projection images where the recording of the first set of X-ray projection images is effected at a plurality of projection angles and finding local image areas assigned to individual vascular segments within a second set of X-ray projection images corresponding to spatial positions of the vascular segments where the recording of the second set of X-ray projection images is effected at a plurality of projection angles. However, this latter technique in *Koppe* utilizes the X-ray projection images of the two series that are formed from each time the same X-ray position through subtraction from one another to form the desired reconstruction sub-image R. This is in contrast to the claimed feature of reconstruction of a three-dimensional structure of the vascular tree using a first set of X-ray projection images where the recording of the first set of X-ray projection images is effected at a plurality of projection angles.

#### b. Claims 8-10 and 12

The Examiner rejected claims 8-10 and 12 under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 6,442,235 to Koppe in Niew of United States Patent No. 7,180,976 to Wink. The Examiner asserted that Koppe includes all of the features of independent claim 8 except for the recording and utilization of any ECG in the imaging process. The Examiner asserted that it would have been obvious to modify Koppe with utilization of ECG recordings as described in claim 8 according to Wink in order to "determine the optimal viewing of the coronary tree" and in order to "improve volumetric reconstruction." (Final Office Action page 5, first paragraph). The Examiner also conceded that Koppe obtains its second set of x-ray images from a fixed position when utilizing dual x-ray detectors but asserts that when a single x-ray detector is utilized then two sets of x-ray images are taken from a plurality of projection angles. (Advisory Action page 2).

Claim 8 includes the features of recording a first set of X-ray projection images of the vascular tree during various phases of a heart cycle while simultaneously recording a first ECG (WP487234;1)

of the patient; recording of a second set of X-ray projection images of the vascular tree during or after administration of a contrast agent while a second ECG of the patient is being recorded; and determining a time-dependent concentration of the contrast agent within the three-dimensional reconstructed structure of the vascular tree by aa) assignment of the X-ray projection images of the second set to a respective phase of the heart cycle using the recorded second ECG; bb) finding local image areas assigned to the individual vascular segments within the X-ray projection images of the second set corresponding to spatial positions of the vascular segments in the respective phase of the heart cycle according to the three-dimensional structure of the vascular tree; and cc) determining the concentration of the contrast agent within the vascular segments by evaluating an X-ray absorption within the local image areas found in the method step bb).

Applicants disagree with the Examiner's conclusion of obviousness and assert that modifying Koppe to include the claimed recording and utilization of ECG signals is mere hindsight analysis. Koppe is directed towards a method of imaging blood flow as a function of time:

The invention is based on the recognition of the fact that an image data set, which may be a two-dimensional of a three-dimensional image data set and contains information concerning the course of the blood vessels in the object to be examined, can be encoded in time in such a manner that it also contains information concerning the blood flow as a function of time. Such encoding in time is performed according to the invention in that the image data set is compared with a series of X-ray projection images; these X-ray projection images are formed successively in time and contain the information concerning the distribution of an injected contrast medium in the blood vessels at each time a different instant. Because each X-ray projection image is andividually compared with the image data set, that is, each image value of the image data set is compared with the image values of the individual X-ray projection images, it is quasi checked which parts of the individual X-ray projection images, it is quasi checked which parts of the vascular system contained in the image data set are filled with the contrast medium at the individual instants associated with the respective X ray projection images. Using suitable reproduction methods, the image data set thus encoded in time can be converted into one or more images which show the blood flow as

(WP487234;1)

h

a function of time. (Koppe col. 1, line 48 through col. 2, line 3)(emphasis added).

One of ordinary skill in the art would not replace the particular technique and sequenced steps described in *Koppe* with the claimed steps of assigning of a second set of X-ray projection images to a respective phase of the heart cycle using a recorded second ECG; finding local image areas assigned to the individual vascular segments within the second set of X-ray projection images corresponding to spatial positions of the vascular segments in the respective phase of the heart cycle according to the three-dimensional structure of the vascular tree; and determining the concentration of the contrast agent within the vascular segments by evaluating an X-ray absorption within the local image areas found.

Additionally, Wink is directed towards a method of three-dimensional reconstruction imaging using rotational angiography:

The presented novel method includes creation of a surface model of a selected segment of interest of the cardiac arterial tree based on projections from a rotational acquisition. The method has the potential to build a model based on every projection that captures the heart at the same phase. The combination of the partial model of the segment of interest with the automatic volumetric reconstruction of the entire coronary tree using all of the acquired projections, without regard to the cardiac phase, is used for visualization of the main vessels of the coronary tree and to determine the optimal working view with reduced vessel overlap and without the need to manually create a surface model of the entire coronary tree, thereby reducing reconstruction time making the process more useful for real time clinical application. (Wink col. 5, lines 44-58)(emphasis added).

The objective of Koppe is to "enable[] the reproduction of the blood flow in an object to be examined as a function of time" which is accomplished by "time encoding of the X-ray image data set." (Koppe col. 1, lines 33-37 and col. 2, lines 17-18). As pointed out above, Wink describes combining a partial vascular model with a complete volumetric reconstruction of the coronary tree without regard to the cardiac phase for visualization and optimal working view.

[WP487234;1]

7

One of ordinary skill in the art would not look towards modifying Koppe to include the recording and utilization of ECG signals based on the Examiner's suggested modification of determining an optimal view or improving volumetric reconstruction. "The TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence – teachings, suggestions (a tellingly broad term), or motivations (an equally broad term) – that arise before the time of invention as the statute requires." Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories 2007-1223 p. 11 (Fed. Cir. March 31, 2008)

Moreover, claims 1-7 include the features of recording a first set of X-ray projection images of the vascular tree during various phases of a heart cycle while simultaneously recording a first ECG of the patient, where the recording of the first set of X-ray projection images is performed at a plurality of projection angles; reconstruction of a three-dimensional structure of the vascular tree during the various phases of the heart cycle from the first set of X-ray projection images; and recording of a second set of X-ray projection images of the vascular tree during or after administration of a contrast agent while a second ECG of the patient is being recorded, where the recording of the second set of X-ray projection images is performed at a plurality of projection angles. Koppe describes a first technique for imaging blood flow as a function of time as follows:

The invention will be illustrated hereinafter on the basis of the flow chart of a first version of the method according to the invention which is shown in FIG. 2. After the initialization (step 100) and after a contrast medium injection, the C-arm 10 is step wise rotated about its center and at the same time a series of m X-ray projection images D<sub>i</sub> (for example, m=100) is formed, which projection images represent the object 3 to be examined and the blood vessels that are present therein and are filled with a contrast medium, from different perspectives (step 101). The X-ray projection images D<sub>i</sub> constitute a three-dimensional X-ray image data set K.

During a step 102 which takes place at the same time or at a later instant (after a further contrast medium injection), the imaging unit 12', 13' acquires a second series of X ray projection images E<sub>i</sub> from a fixed perspective. During the subsequent step 103 on the one hand correction is made for imaging errors which are due, for example, to the

imperfection of the imaging device of to the mechanical deformation of the C-arm. On the other hand a three-dimensional reconstruction image R is formed from the X-ray projection images D<sub>i</sub> by means of a known reconstruction algorithm. In the step 104 a reconstruction sub-image R' is formed from said reconstruction image R, which reconstruction sub-image contains, mainly or exclusively, information concerning the course of the blood vessels in the region examined. This reconstruction sub-image R' contains q voxels V<sub>k</sub> which are characterized by their co-ordinates in space. (Koppe col. 4, lines 28-55)(emphasis added).

Koppe further describes another reconstruction technique as follows:

A reconstruction sub-image R' can also be obtained in a manner other than that described with reference to FIG 2; for example, by subtraction angiography. To this end, two series of X-ray projection images are formed from different X-ray positions by means of the imaging unit 12, 13, that is, once with and once without administration of contrast medium. The X-ray projection images of the two series that are formed from each time the same X-ray position are then subtracted from one another and the resultant projection images are reconstructed so as to form the desired reconstruction sub-image R' (Koppe col. 6, lines 3-13).

This latter technique in *Koppe* is relied upon by the Examiner for describing the claimed features of recording a first set of X-ray projection images of the vascular tree during various phases of a heart cycle while simultaneously recording a first ECG of the patient, where the recording of the first set of X-ray projection images is performed at a plurality of projection angles; reconstruction of a three-dimensional structure of the vascular tree during the various phases of the heart cycle from the first set of X-ray projection images and recording of a second set of X-ray projection images of the vascular tree during or after administration of a contrast agent while a second ECG of the patient is being recorded, where the recording of the second set of X-ray projection images is performed at a plurality of projection angles. However, this latter technique in *Koppe* utilizes the X-ray projection images of the two series that are formed from each time the same X-ray position through subtraction from one another to form the desired reconstruction sub-image R.

This is in contrast to the claimed feature of reconstruction of a three-dimensional structure of the vascular tree during the various phases of the heart cycle from the first set of X-ray projection images.

### VIII. CLAIMS APPENDIX

X-ray imaging device with computer means which is provided for visualizing blood flow 1. in a coronary vascular tree of a patient such that the visualization is effected based on data which contain a first set of X-ray projection images of the vascular tree in various phases of a heart cycle, a first ECG of the patient recorded simultaneously with the first set, a second set of X-ray projection images recorded during or after administration of a contrast agent and a second ECG of the patient recorded simultaneously with the second set, which computer means comprise a program control which operates in accordance with the following method steps for determining a time-dependent concentration of the contrast agent within a three-dimensional structure of the vascular tree:

reconstruction of the three-dimensional structure of the vascular tree during the various phases of the heart cycle using the first set of X-ray projection images and splitting of the structure into a number of vascular segments;

determining the time-dependent concentration of the contrast agent within the reconstructed three-dimensional structure of the vascular tree by

- aa) assignment of the second set of X projection images to a respective phase of the heart cycle using the recorded second ECG;
- bb) finding local image areas assigned to the individual vascular segments within sponding to spatial positions of the the second set of X-ray projection images confe vascular segments in the respective phase of the heart cycle according to the threedimensional structure of the vascular tree;
- cc) determining the concentration of the contrast agent within the vascular segments by evaluating an X-ray absorption within the local image areas found in the method step bb); and

visualization of flow of the contrast agent through the three-dimensional structure of the vascular tree according to the time-dependent concentration of contrast agent, wherein the recording of the first and second set of X-ray projection images is effected at a plurality of projection angles.

- 2. X-ray imaging device as claimed in claim 1, wherein the second set of X-ray projection images is recorded during or after the administration of the contrast agent, while the vascular tree fills with the contrast agent and then the first set of X-ray projection images is recorded after the vascular tree is completely filled with the contrast agent.
- 3. X-ray imaging device as claimed in claim 1, further comprising means for generating the first and the second set of X-ray projection images of the coronary vascular tree of the patient under various projection directions and means for recording the ECG of the patient during the recording of the first and second sets of X-ray projection images.
- 4. X-ray imaging device as claimed in claim 2, wherein the computer means are arranged such that during or after the administration of the contrast agent the second set of X-ray projection images is recorded while the vascular tree fills with contrast agent, and subsequently the first set of X-ray projection images is recorded, after which the vascular tree completely fills with the contrast agent.
- 5. X-ray imaging device as claimed in claim 2, wherein the computer means are further arranged such that the recording of the first and second set of X-ray projection images at the plurality of projection angles is by means of continuous rotation X-ray imaging.
- 6. X-ray imaging device as claimed in claim 1, wherein the computer means are arranged such that for reconstructing the three-dimensional structure of a computer-aided modeling of the vascular tree is effected while eliminating the other anatomical structures contained in the first set of X-ray projection images.

7. Computer program for an X-ray imaging device for visualization of the blood flow in a coronary vascular tree of a patient, wherein the computer program receives as input variables data which contain a first set of X-ray projection images of the vascular tree in various phases of a heart cycle, a first ECG of the patient recorded simultaneously with the first set, a second set of X-ray projection images recorded during or after the administration of a contrast agent and a second ECG of the patient recorded simultaneously with the second set, which computer program on the computer means of the X-ray imaging device implements a program control which operates in accordance with the following method steps for determining a time-dependent concentration of the contrast agent within a three-dimensional structure of the vascular tree:

reconstruction of the three-dimensional structure of the vascular tree during the various phases of the heart cycle using the first set of X-ray projection images and splitting of the structure into a number of vascular segments;

determining the time-dependent concentration of the contrast agent within the reconstructed three-dimensional structure of the vascular tree by

- aa) assignment of the X-ray projection images of the second set to a respective phase of the heart cycle using the recorded second ECG;
- bb) finding local image areas assigned to the individual vascular segments within the X-ray projection images of the second set that correspond to spatial positions of the vascular segments in the respective phase of the heart cycle according to the three-dimensional structure of the vascular tree;
- cc) determining the concentration of the contrast agent within the vascular segments by evaluating an X-ray absorption within the local image areas found in the method step bb);

visualization of flow of the contrast agent through the three-dimensional structure of the vascular tree according to the time-dependent concentration of the contrast agent, wherein the recording of the first and second set of X-ray projection images is effected at a plurality of projection angles.

- 8. X-ray imaging method for visualizing blood flowing a coronary vascular tree of a patient having the following method steps:
- a) recording a first set of X-ray projection images of the vascular tree during various phases of a heart cycle while simultaneously recording a first ECG of the patient, the recording of the first set of X-ray projection images being performed at a plurality of projection angles;
- b) reconstruction of a three-dimensional structure of the vascular tree during the various phases of the heart cycle from the first set of X-rey projection images and splitting of the structure into a number of vascular segments;
- c) recording of a second set of X-ray projection images of the vascular tree during or after administration of a contrast agent while a second ECG of the patient is being recorded, the recording of the second set of X-ray projection images being performed at a plurality of projection angles;
- d) determining a time-dependent concentration of the contrast agent within a three-dimensional structure of the vascular tree as reconstructed in the method step b) by
  - aa) assignment of the X-ray projection images of the second set to a respective phase of the heart cycle using the recorded second ECG;
  - bb) finding local image areas assigned to the individual vascular segments within the X-ray projection images of the second set emessional to spatial positions of the vascular segments in the respective phase of the heart cycle according to the three-dimensional structure of the vascular tree;
  - cc) determining the concentration of the contrast agent within the vascular segments by evaluating an X-ray absorption within the local image areas found in the method step bb);
- e) visualization of flow of the contrast agent through the three-dimensional structure of the vascular tree according to a time-dependent concentration of the contrast agent determined in method step d).

- 9. X-ray imaging method as claimed in claim 8, wherein the second set of X-ray projection images is recorded during or after the administration of the contrast agent, while the vascular tree fills with the contrast agent and then the first set of X-ray projection images is recorded after the vascular tree is completely filled with the contrast agent.
- 10. X-ray imaging method as claimed in claim 8, wherein the recording of at least one of the first and second set of X-ray projection images is effected using continuous rotation X-ray imaging at a plurality of projection angles.
- 12. X-ray imaging method as claimed in claim 8, wherein a computer-aided modeling of the vascular tree, with elimination of other anatomical structures contained in the first set of X-ray projection images, is effected to reconstruct the three-dimensional structure in method step b).

### IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

### CONCLUSION

For at least the reasons given above, claims 1110 and 12 define patentable subject matter and are thus allowable. The Applicant requests withdrawal of the rejections and allowance of the claims.

ctfully submitted,

Registration No. 47,620

man Senterfitt

for Douglas B. McKnight, Reg. No. 50,447 ps Electronics North America Corporation

595 Miner Road Cleveland, Ohio 44143 Telephone: 440-483-2373 Facsunile: 440-483-2452

File PHDE030127US

(WP487234;1)